



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS



28 JUNE 2017

MEMORANDUM FOR 959 MDOS
ATTN: MAJ ADRIENNE LAURY

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Balloon Catheter Dilation for the Treatment of "Sinus Pressure" Headaches** presented at/published to **Otolaryngology – Head and Neck Surgery & AAO-HNS Annual Meeting, 11, Sept 10-13, 2017**
2. in accordance with MDWI 41-108, has been approved and assigned local file #**17270**.
3. Pertinent biographic information (name of author(s) title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
4. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.
5. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]
 - b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.
3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.
4. Attach a copy of your abstract, paper, poster and other supporting documentation.
5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.
7. Submit your completed form and all supporting documentation to the CRD for processing to: usaf.jbsa.59-mdw.mbx.wing-crd-publications-and-presentations@mail.mil. **This should be accomplished no later than 30 days before final clearance is required to publish/present your materials.** If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.
8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers*, for additional information.
11. The Joint Ethics Regulation (JER) DoD 5500.07-R, *Standards of Conduct*, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. **If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review.** To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:

"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:

"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN

40-401_IP :

"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS			
1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol) Laury, Adrienne M, Maj	3. GME/GHSE STUDENT: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	4. PROTOCOL NUMBER: FWH20150103H
5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.) The Effects of Balloon Sinuplasty on Barometric Pressure "Sinus" Headaches			
6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: Balloon Catheter Dilation for the Treatment of "Sinus Pressure" Headaches			
7. FUNDING RECEIVED FOR THIS STUDY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO FUNDING SOURCE:			
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
9. IS THIS MATERIAL CLASSIFIED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.			
11. MATERIAL IS FOR: <input checked="" type="checkbox"/> DOMESTIC RELEASE <input type="checkbox"/> FOREIGN RELEASE CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.			
<input type="checkbox"/> 11a. PUBLICATION/JOURNAL (List intended publication/journal.)			
<input checked="" type="checkbox"/> 11b. PUBLISHED ABSTRACT (List intended journal.) Otolaryngology - Head and Neck Surgery			
<input type="checkbox"/> 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)			
<input checked="" type="checkbox"/> 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting.) AAO-HNS Annual Meeting, II, Sept 10-13, 2017			
<input type="checkbox"/> 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)			
12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO ASSIGNED FILE # _____ DATE _____			
13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).			
DATE June 26, 2017			
14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Laury, Adrienne, M, adrienne.m.laury.mil@mail.mil			15. DUTY PHONE/PAGER NUMBER 610-533-1282
16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.			
LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Laury, Adrienne M	Maj	959 MDOS	SAMMC
b.			
c.			
d.			
e.			
17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.			
18. AUTHOR'S PRINTED NAME, RANK, GRADE Adrienne Laury, Maj		19. AUTHOR'S SIGNATURE LAURY ADRIENNE M.1280383062	20. DATE 6/21/2017
21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Alex McKinlay, Lt Col		22. APPROVING AUTHORITY'S SIGNATURE MCKINLAY.ALEX.J.1013683103	23. DATE 6/21/2017

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS		
1st ENDORSEMENT (59 MDW/SGVU Use Only)		
TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	24. DATE RECEIVED June 21, 2017	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17270
26. DATE REVIEWED 23 Jun 2017	27. DATE FORWARDED TO 502 ISG/JAC	
28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES If yes, give date. <u>23 Jun 2017</u> <input type="checkbox"/> N/A		
29. COMMENTS <input checked="" type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED The author provided their research authorization letter and added the human research disclaimer statement to their presentation. The presentation is approved.		
30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Rocky Calcote, PhD, Clinical Research Administrator	31. REVIEWER SIGNATURE CALCOTE ROCKY D. 1178245844 <small>Digitally signed by CALCOTE ROCKY D. 1178245844 DN: cn=US, email=S. Government, ou=CRD, ou=PM, ou=USAF cn=CALCOTE ROCKY D. 1178245844 Date: 2017.06.28 09:30:43 -0500</small>	32. DATE
2nd ENDORSEMENT (502 ISG/JAC Use Only)		
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35. COMMENTS <input type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED		
36. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	37. REVIEWER SIGNATURE	38. DATE
3rd ENDORSEMENT (59 MDW/PA Use Only)		
39. DATE RECEIVED June 28, 2017	40. DATE FORWARDED TO 59 MDW/SGVU June 28, 2017	
41. COMMENTS <input checked="" type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED		
42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Kevin Inuma, SSgt/E-5, 59 MDW Public Affairs	43. REVIEWER SIGNATURE IINUMA KEVIN MITSUGU.1296227 613 <small>Digitally signed by IINUMA KEVIN MITSUGU.1296227 DN: cn=US, email=S. Government, ou=CRD, ou=PM, ou=USAF cn=IINUMA KEVIN MITSUGU.1296227 Date: 2017.06.28 12:06:54 -0500</small>	44. DATE June 28, 2017
4th ENDORSEMENT (59 MDW/SGVU Use Only)		
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Balloon Catheter Dilation for the Treatment of “Sinus Pressure” Headaches

Adrienne M. Laury MD

May 19, 2017

Disclaimer

- The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, the Department of the Air Force and Department of Defense or the U.S. Government.

The views expressed are those of the author(s)/presenter(s) and do not reflect the official views or policy of the Department of Defense or its Components.

Background

- Barometric pressure/ “sinus” headache is a relatively common phenomenon
- Definition: Sensation of pressure or pain in the head/face overlying the paranasal sinuses exacerbated by changes in barometric pressure or weather patterns
- Must be differentiated from other common headache pathologies ie. Migraine, cluster, tension, medication overuse, etc

Background

- Balloon catheter dilation of sinus ostia – procedure which dilates the ostia of the sinuses (maxillary, frontal, and/or sphenoid)
- FDA approved in 2006 and predominantly studied and utilized for the treatment of chronic and acute rhinosinusitis

Clinical Question

- Does balloon catheter dilation of sinus ostia effect the severity or frequency of “sinus”/barometric pressure related headaches

Methods

- Patients with barometric pressure related headaches were recruited.
- Patients underwent CT of the sinuses and were required to have a Lund-Mackay score of 0
- Patients were given HIT-6 and SNOT-22 questionnaires as well as medication log to document all headache medications

HIT-6

1. When you have headaches, how often is the pain severe?

Never Rarely Sometimes Very often Always

2. How often do headaches limit your ability to do usual daily activities including household work, work, school, or social activities?

Never Rarely Sometimes Very often Always

3. When you have a headache, how often do you wish you could lie down?

Never Rarely Sometimes Very often Always

4. In the past 4 weeks, how often have you felt too tired to do work or daily activities because of your headaches?

Never Rarely Sometimes Very often Always

5. In the past 4 weeks, how often have you felt fed up or irritated because of your headaches?

Never Rarely Sometimes Very often Always

6. In the past 4 weeks, how often did headaches limit your ability to concentrate on work or daily activities?

Never Rarely Sometimes Very often Always

Methods

- Patients with barometric pressure related headaches were recruited.
- Patients underwent CT of the sinuses and were required to have a Lund-Mackay score of 0
- Patients were given HIT-6 and SNOT-22 questionnaires as well as medication log to document all headache medications
- Clinically meaningful response – HIT-6 decrease of 6 points and SNOT-22 decrease of 8.9

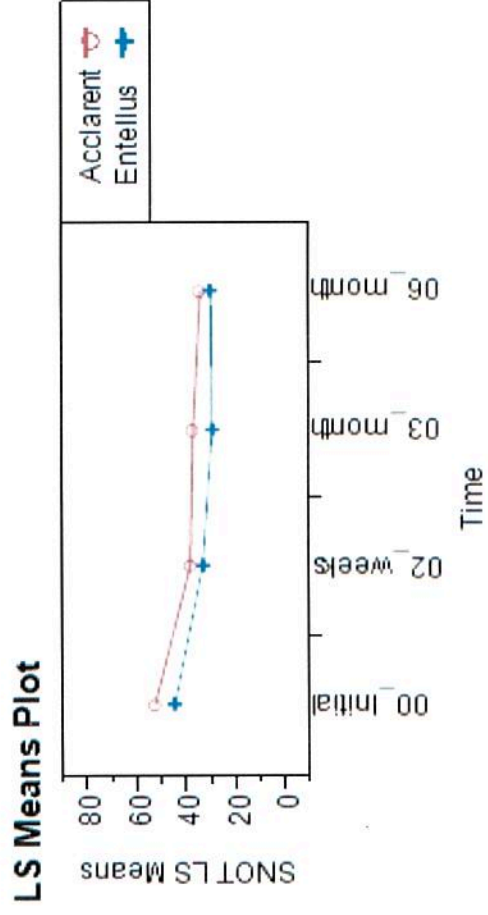
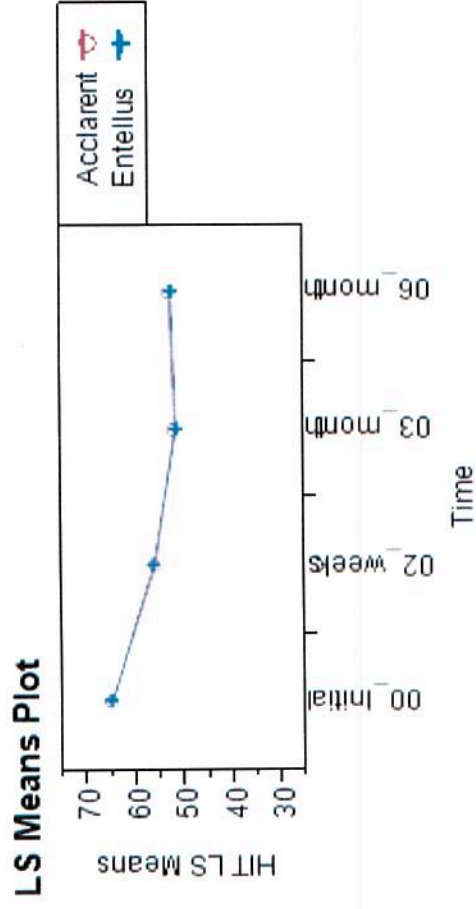
Methods

- Patients were blinded and randomized to either balloon catheter dilation of “affected” sinuses vs nasal dilation in the clinic with 2 different brands of balloon devices
- Post-op antibiotics, medrol dosepak, and Norco were given to all patients
- Followed-up for complications and repeat questionnaires and medication logs at 2 weeks, 3 months, and 6 months post

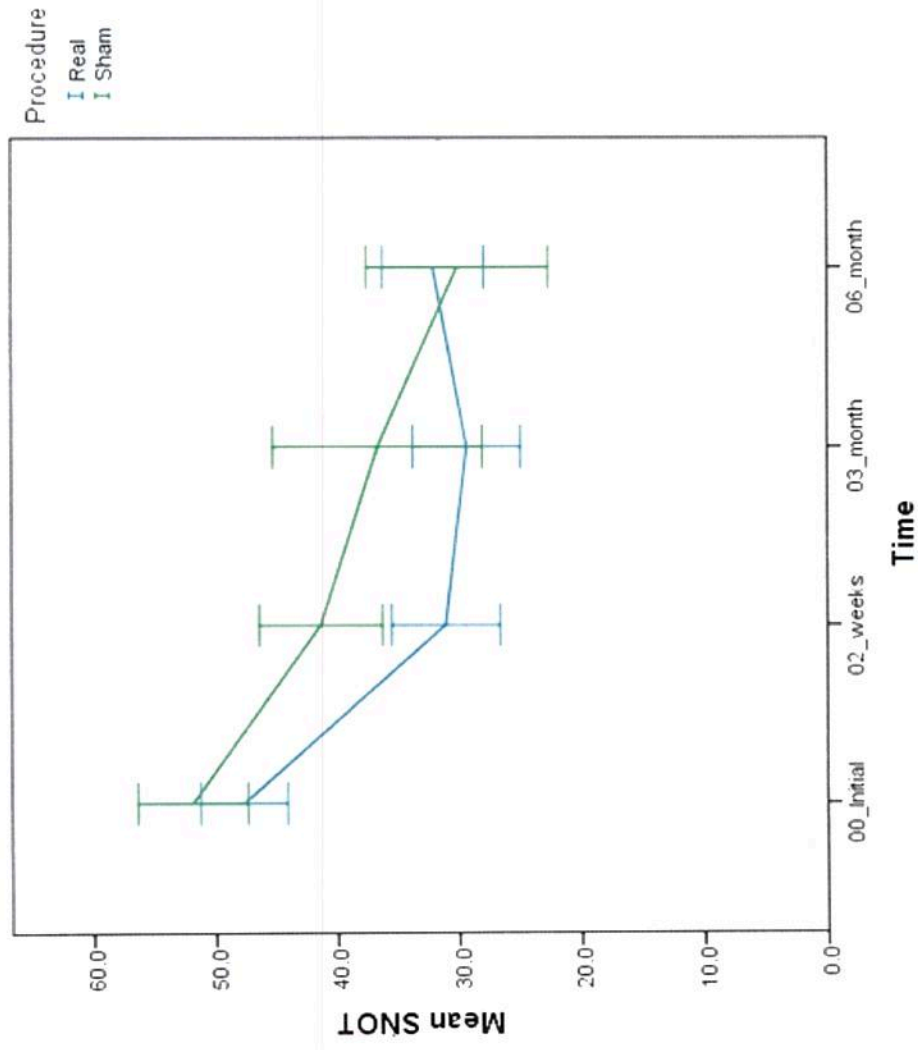
Results

- 34 patients were recruited and underwent the procedure (27 female vs 7 male)
- 18 underwent balloon catheter dilation vs 16 underwent nasal dilation
- Complications: 4 patients had post-op infections (2 balloon and 2 dilation)

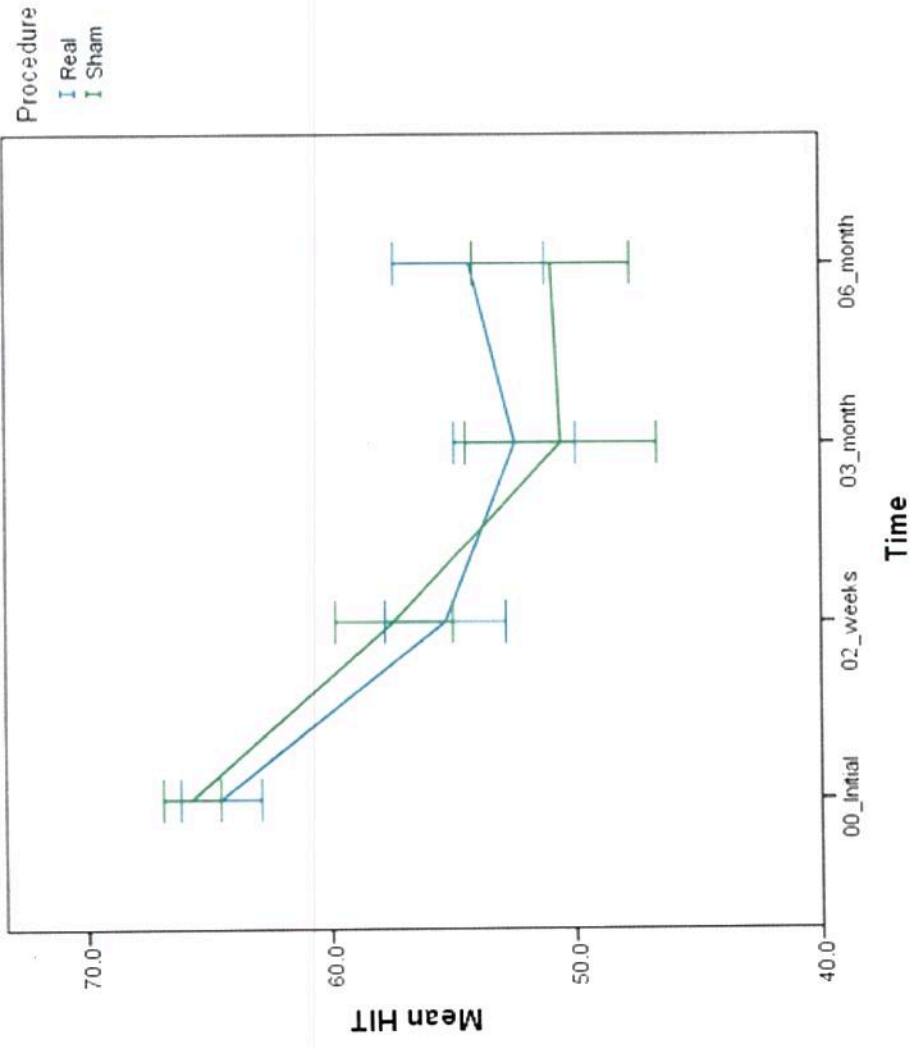
Results - Device



Results – SNOT 22

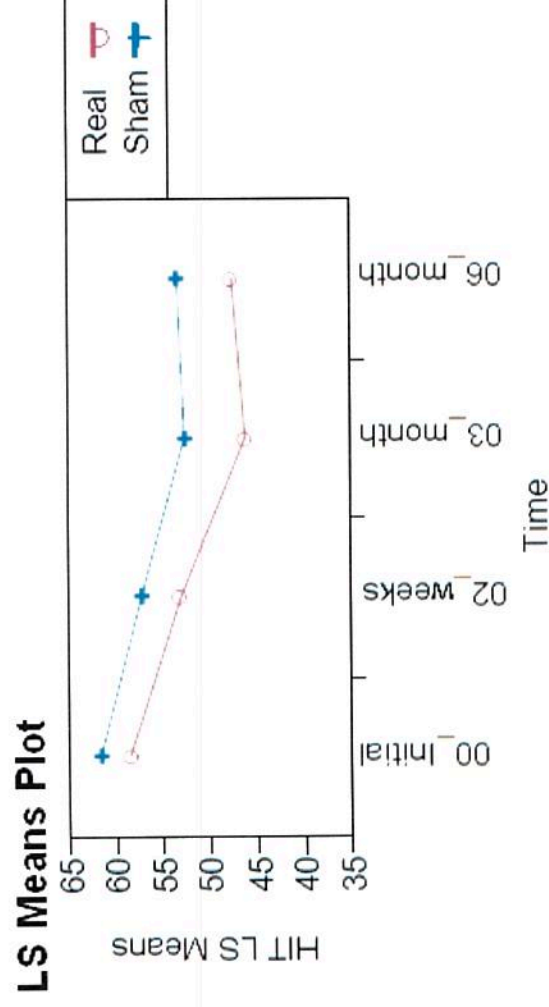


Results – HIT-6

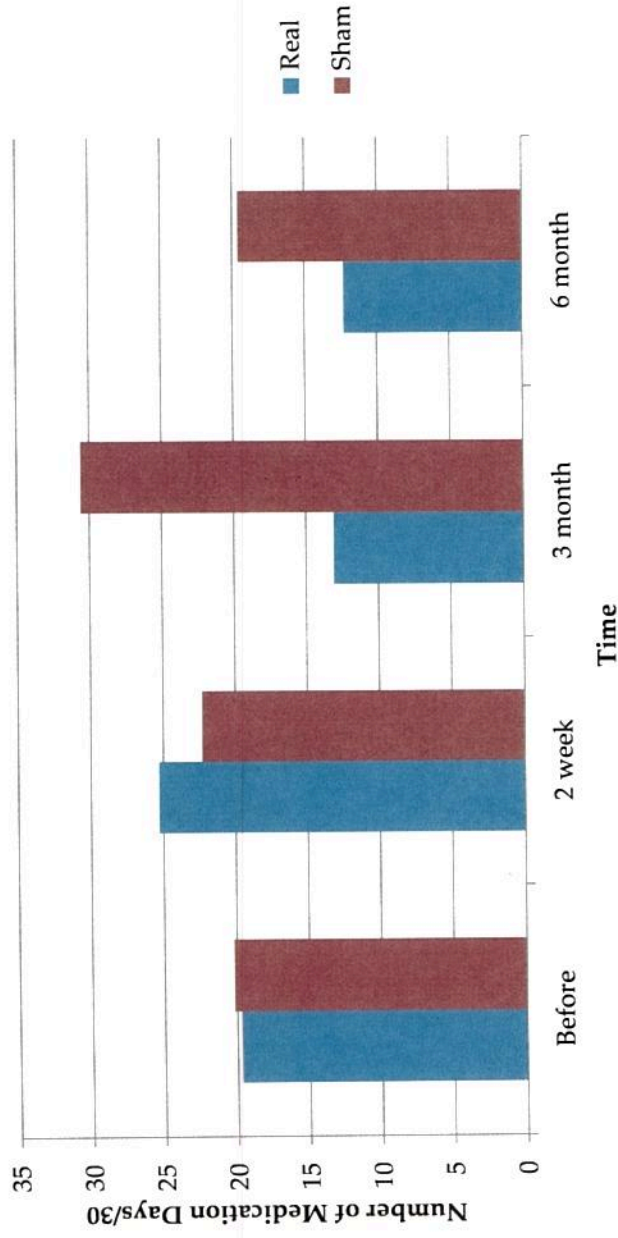


Results – HIT-6 ≥ 65

$p = 0.08$



Results – Medication Use



Conclusion

- Balloon catheter dilation and nasal dilation both appear to provide clinically significant improvement in SNOT-22 and HIT-6 scores in patients with sinus pressure headaches
- Entellus and Acclarent devices provide equivocal results
- Further investigation is needed in patients with more severe headaches (HIT-6 >65) regarding the utility of balloon catheter dilation and with regard to changes in medication utilization